18 Nov 2016

To
Dr. Rajib Paul,
Principal Investigator,
Apollo Hospitals,
Jubilee Hills,
Hyderabad-500 096

Ref: Application No: AHJ-020/09-16

Protocol No: CYT01/2016

Title: An Investigator initiated Observational Study to evaluate the Clinical outcome with Extracorporeal Cytokine Adsorption Device (Cytosorb) in the setting of Sepsis and Septic shock patients

Sub: Your letter dated 19 Oct 2016 for the approval of the study related documents.

Dear Dr. Rajib Paul,

The Institutional Ethics Committee- Clinical Studies, Apollo Hospitals, Hyderabad, reviewed and discussed the documents submitted by you related to the conduct of the above referenced study at its meeting held on 12 Nov 2016.

Documents Submitted:

S.No	Contents	Version and Date
1.	Protocol	version no.:1, Final
2.	Case Record form	Version No.:1
3.	Patient information sheet and informed consent form-English	Version 1
4.	Patient information sheet and informed consent form-Hindi and back translation of Patient information sheet and informed consent form	Version 1 dated 20 Jul 2016 and back translation version 1 dated 29 Aug 2016
5.	Patient information sheet and informed consent form-Telugu and back translation of Patient information sheet and informed consent form	Version 1dated 08 Aug 2016 and back translation version 1 dated 29 Aug 2016
6.	Certificate of translation and verification-English to telugu	Dated 10 Aug 2016
	Certificate of translation and verification and English to Hindi	Dated 21 Jul 2016

7.	Certificate of insurance	-
8.	Certificate of Back translation and verification-telugu to English	Dated 30 Aug 2016
9.	Certificate of Back translation and verification-Hindi to English	Dated 29 Aug 2016
10.	Certificate from the management system of cytosorbents	Expiry date:31 Dec 2018
11.	Clarification from CDSCO regarding Import of non-notified medical devices	-
12.	CTRI registration	REF/2016/08/011924
13.	Case series and case reports	-
14.	Letter of Intent	-

- PIs declaration regarding "conflict of interest".

The following Institutional Ethics Committee- Clinical Studies members were present at the meeting held on 12 Nov 2016 at 3:00 P.M at Board Room – Clinical Trials Unit, Apollo Hospitals, Hyderabad-96.

S. NO	NAME	GENDER	DESIGNATION	AFFILIATION WITH INSTITUTION (YES / NO)	POSITION IN THE COMMITTEE
1.	Mr. K Satyanarayana Rao	M	Advocate, AP High Court	No	Chairperson (Lawyer)
2.	Dr. Alekhya.A	F	Clinical Pharmacologist	Yes	Member Secretary (Pharmacologist)
3.	Dr. V.K. Bhargava	M	Sr. Consultant, Internal Medicine	Yes	Clinician
4.	Dr. Ravindra Babu	M	Medical Superintendent	Yes	Clinician
5.	Mr. Rasheeduddin Aijaz	M	Advocate, Private Practice	No	Lawyer
6.	Ms. Prema Edwards	F	Retired School Principal	No	Lay Person
7.	Mr. Shafath Ahmed Khan	M	Advocate, Private Practice	No	Lawyer
8.	Dr. Vishnu Vardhana Rao	M	Scientist 'F'/Sr. Dy. Director, National Institute of Nutrition(ICMR)	No	Statistician
9.	Dr. Sudhir Naik	M	Consultant Cardiologist	Yes	Clinician
10.	Ms. C.S. Jyothi	F	Prior experience as Social Worker	No	Social Worker

11.	Ms. Vandana Rajkumar	F	Sr. Process Executive, Cognizant.	No	Lay Person
12.	Mr. Buchan Reddy	M	Freelancer- Social work Documentation	No	Social Worker

After due ethical and scientific consideration, the Ethics Committee has suggested the following changes in the ICF:

1. Compensation should be mentioned.
2. Details of PI and EC Chairperson is missing in English and translations/back translation
3. Total number of centers participating in the study is not mentioned.

Following are the changes suggested in the protocol:

1. As there is intervention involved in the study, the word "observational" from the study title should be removed in all study documents.
2. Dose modification of drugs with (10-55kDa) should be mentioned, as PK/PD characters of many drugs are altered by therapy.

The following document needs to be submitted by you for review and final approval before the study can be initiated:

- CV, MRC, GCP training certificates of PI and study team members.

The Institutional Ethics Committee- Clinical Studies is constituted and works as per the ICH-GCP, ICMR and revised Schedule Y guidelines.

Yours Sincerely,

Dr. Alekhya. A,
Member Secretary,
Institutional Ethics Committee- Clinical Studies,
Apollo Hospitals,
Hyderabad, India

Date: 18.11.16
Place: Hyderabad

IEC Application No.: AHJ-020/09-16

(Note: Please mention this application no. in all your future communications).

Status:
1. Approved in principle/ ~~A~~pproved with suggestions or query
2. Disapproved.

28 Jan 2017

To
Dr. Rajib Paul,
Principal Investigator,
Apollo Hospitals,
Jubilee Hills,
Hyderabad-500 096

Ref: Application No: AHJ-020/09-16

Protocol No: CYT01/2016

Title: An Investigator Initiated Study to evaluate the Clinical outcome with Extracorporeal Cytokine Adsorption Device (Cytosorb) in the setting of Sepsis and Septic shock patients.

Sub: Final Full Board Approval (Subsequent to your letter dated 09 Jan 2017)

Dear Dr. Rajib Paul,

The Institutional Ethics Committee- Clinical Studies, Apollo Hospitals, Hyderabad, reviewed and discussed the documents submitted by you related to the conduct of the above referenced study at its meeting held on 21 Jan 2017.

Documents Submitted:

S.No	Contents	Version and Date
1.	Protocol	version no.:2
2.	Case Record form	Version No.:2
3.	Patient information sheet and informed consent form-English	Version :2 dated 22-12-2016
4.	Patient information sheet and informed consent form-Hindi and back translation of Hindi Patient information sheet and informed consent form	Version 2 dated 23 Dec 2016and back translation version 2 dated 23 Dec 2016
5.	Patient information sheet and informed consent form-Telugu and back translation of Telugu Patient information sheet and informed consent form	Version 2 dated 23 Dec 2016and back translation version 2 dated 23 Dec 2016
6.	Certificate of translation and verification-	Dated 23 Dec 2016

	English to telugu and English to Hindi	Dated 23 Dec 2016
7.	Certificate of Back translation and verification-telugu to English and Hindi to English	Dated 23 Dec 2016
		Dated 23 Dec 2016

- A copy of CV, MRC and GCP certificate of PI.

The following Institutional Ethics Committee- Clinical Studies members were present at the meeting held on 21 Jan 2017 at 3:00 P.M at Board Room – Clinical Trials Unit, Apollo Hospitals, Hyderabad-96.

S. NO	NAME	GENDER	DESIGNATION	AFFILIATION WITH INSTITUTION (YES / NO)	POSITION IN THE COMMITTEE
1.	Mr. K Satyanarayana Rao	M	Advocate, AP High Court	No	Chairperson (Lawyer)
2.	Dr. Alekhya.A	F	Clinical Pharmacologist	Yes	Member Secretary (Pharmacologist)
3.	Dr. V.K. Bhargava	M	Sr. Consultant, Internal Medicine	Yes	Clinician
4.	Mr. Rasheeduddin Aijaz	M	Advocate, Private Practice	No	Lawyer
5.	Ms. C.S. Jyothi	F	Prior experience as Social Worker	No	Social Worker
6.	Ms. Vandana Rajkumar	F	Sr. Process Executive, Cognizant	No	Lay Person

After due ethical and scientific consideration, the Ethics Committee has approved all the documents and the study to be conducted by you in the presented form.

Prior to site initiation, the list of team members has to be submitted to the Ethics Committee.

Please note that the date of initiation of the study, the date of first patient participation and the date of last patient participation should be informed to the Ethics Committee. The Ethics Committee should be informed about the progress of the study on **half yearly basis.** Any changes in the protocol and patient information / informed consent, and a copy of the final clinical study report should be provided.

Please note the period of validity of this Approval is for one calendar year and ends on 27 Jan 2018.

The Institutional Ethics Committee – Clinical Studies is constituted and works as per ICH-GCP, ICMR and revised Schedule Y guidelines.

Yours Sincerely,

Dr. Alekhya. A,
Member Secretary,
Institutional Ethics Committee- Clinical Studies,
Apollo Hospitals,
Hyderabad, India

Date: 28.1.17
Place: Hyderaba

Status: Final Full Board Approval

POONA MEDICAL RESEARCH FOUNDATION

Institutional Ethics Committee

E4-C to E4-F 4th Floor, Fifth Avenue, Condomonium, Dhole Patil Road, Pune - 411 001.

Date: 18th November 2016

To,
Dr. Prachee Sathe
Intensivist
Ruby Hall Clinic
40, Sassoon Road
Pune- 411001

Reference : An Investigator Initiated Observational study to evaluate the Clinical outcome with Extracorporeal Cytokine Adsorption Device(CytoSorb) in the setting of sepsis and septic shock patients.

Subject : Institutional Ethics Committee approval for the conduct of the above mentioned study.

Dear Dr. Sathe,

We have received 10 copies of the Following documents:

- Clinical Study Protocol Version 1
- Case Record Form Version 1
- English - Patients Information Sheet & Informed Consent Form Version1
- English to Hindi- Patients Information Sheet & Informed Consent Form Version1 dt 20 July 2016.
- Draft Clinical trial Agreement

At the Ethics Committee meeting held at Conference Hall, E4-C to E4-F 4th floor, 5th Avenue Condominium, Dhole Patil Road, Pune- 411 001 on **17th April 2016** at 09.45 am your reference letter and above documents were examined and discussed. After due consideration the committee has decided to approve the conduct at above mentioned protocol to be conducted at Ruby Hall Clinic, 40, Sassoon Road, Pune-411001.

Please ensure that, CTRI registration is done & Registration No is submitted to IEC before patient enrolment start.

The following members who attended the meeting at which your documents were discussed are listed below.

Sr. No.	Name of the Member	Designation	Gender (M/F)	(Scientific/ Non-scientific)	Affiliation with Institution (Y/N)
01	Mr. B P Shaligram	Chairperson	M	Non-scientific	N
02	Dr. R.B. Gulati	Cardiologist	M	Scientific	Y
03	Dr. R S Wadia	Neurologist	M	Scientific	Y

04	Dr. S G Deshpande	Surgeon	M	Scientific	Y
05	Mrs. M. Kulkarni	Legal Expert	F	Non-scientific	Y
06	Mrs. Ranjana Sahasrabudhe	Basic Medical Scientist	F	Scientific	N
07	Mr. S P Mehta	Lay Person	M	Non-Scientific	N
08	Mrs. Surekha Joshi	Social Worker	F	Non-Scientific	Y
09	Mrs. Kalyani C Chavan	Member Secretary	F	Non-Scientific	Y

It is to be noted that neither you nor any of your proposed study team members were present during the decision making procedures of EC.

Please note that the Committee is constituted as per ICH-GCP, Schedule Y, and ICMR guidelines.

The Institutional Ethics Committee expects to be informed about the following –

- Progress of the study on annual basis
- Any Serious Adverse Event occurring in the course of the study
- Any changes in the protocol, patient information/informed consent form and other critical study related documents
- Any protocol deviations
- Copy of the final report

Sincerely,

Mrs. Kalyani Chavan
Member Secretary
Institutional Ethics Committee

Mrs. Kalyani C. Chavan
Member Secretary
Institutional Ethics Committee
Poona Medical Research Foundation
E4-C to E4-F, 5th Floor,
Fifth Avenue, Condomonium
Dhole Patil Road,
Pune - 411 001.